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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,799	12/20/2001	Beuford Arlie Bogue	24720	4794

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/022,799

Applicant(s)

BOGUE, BEUFORD ARLIE

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

RD

DETAILED ACTION

Receipt of amendment and remarks dated 2-4-05 is acknowledged.

The following rejection of record has been maintained:

Claims 1-14 and 18-25 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/40943 (WO).

WO discloses solubilizing delivery systems for poorly soluble drugs and the process of solubilizing the drugs so as to enhance the solubility of the drugs. The process of WO comprises processing of particles of at least one active agent and at least one solubilizing agent (surfactant) at temperatures below the melting points of both drug and surfactant (eutectic temperature). The processing further involves applying shear forces after melting the drug and surfactant at the eutectic temperatures (page 2, lines 20-31; page 3, lines 6-16 and lines 26-30 & page 4, lines 1-3), resulting in crystalline drug particles coated with the surfactant. WO discloses the claimed drugs and surfactants suitable for the invention on page 5 and 6; and their amounts on page 4, lines 17-25, all of which are claimed in the instant application. WO discloses employing micronized drug (example I) for the processing and hence meet claim 21. With respect to the particle size, WO states that the particle size before processing is less than 10 microns or even preferably less than 6 microns (page 5, lines 16-18) and the process of applying high shear, disclosed by WO, inherently yields crystalline particles of much smaller size. The claimed matrix, miscibility and the absence of bonding between the drug and the surfactant is inherent to the composition of WO

because the drug and surfactant are processed in exactly the same way as described in the instant specification. Accordingly, WO anticipates instant claims.

Claim Rejections - 35 USC § 103

Claims 15-17 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/40943 (WO).

WO, discussed above, fails to specifically teach the carrier, diluent, binder etc., for the drug. However, WO suggests mixing the surfactant coated drug particles (after processing) with various pharmaceutical ingredients such as binders, flow control agents, fillers, sweeteners etc. Accordingly, it would have been within the scope of a skilled artisan at the time of the instant invention to include any suitable pharmaceutical additive such as a binder or sweetener depending on the desired pharmaceutical effect.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites limitations "a surfactant-drug matrix at a temperature above said matrix's melting temperature" and "said drug composition further comprises micro or nano-sized crystals of said drug substance coated said surfactant at room temperature, said crystals formed while being said matrix is cooled to room temperature under shearing force", which are indefinite because it is unclear from the above limitations if

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applicants' are claiming a matrix formed by melting at a temperature above the melting temperature of the matrix (a product by process) or a matrix already formed and has a temperature above the melting temperature. If the former is being claimed, then the claim does not clearly state so. With respect to the second limitation, it is examiner's understanding that the drug crystals are coated with the surfactant. However, the expression "drug substance coated said surfactant" is not the same as what is being claimed. A clarification and correction is requested.

Response to Arguments

WO 99/40943: Applicants argue that instant surfactant-drug matrix is formed at a temperature above the matrix's melting temperature, where as the reference cited teaches processing below the melting temperature and preferably below the eutectic of the active and solubilizer. Applicants argue that the active agent and solubilizer of the prior art are not melted together and the reference is concerned with coating of solid particles, that is different from the instant. However, instant claims 1-17 are directed to a product and not a process. Further, WO clearly teaches that the melting point of the solubilizer or combination of solubilizers should be less than the melting point of the active agent. Instant specification also state that the surfactant-drug matrix is melted at the temperature of above matrix melting temperature and yet below the decomposition temperature of the drug. Thus, both instant as well as the WO reference produce the product. Applicants' argument that WO teaches solid particles is not persuasive because instant also claim crystals of the drug, which are in a solid form. Besides, the

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melting temperature referred by WO is the temperature at which active dissolves.

Instant specification also states that the matrix melting temperature is below the melting temperature of the active agent. Accordingly, WO also uses the same temperature for melting (i.e., below the melting temperature of the active agent). WO also teaches applying force (example I), which reads on the instant shear force. Thus, WO anticipates instant claims.

Applicants argue that the WO reference does not teach or suggest Applicant's inventive subject matter as a whole, as recited in the claims. Further, there is no teaching or suggestion in this reference, which would lead the ordinary skilled artisan to modify the reference to arrive at the amended claims. Applicants argue that claims 15-17 and 26-28 depend from independent claims and 18, respectively, and therefore necessarily contain all of the limitations found therein. It is argued that for the reasons explained (as in the above paragraph), claims are not obvious over the WO reference. Applicants submit that the reference fails to disclose the limitations of a matrix from at a temperature above its melting temperature and crystal coated with surfactant which are grown by shearing the melted matrix while cooling to room temperature. However, as explained above, WO does teach the claimed product as well as process and for the reasons explained in the previous action, instant claims 15-17 and 26-28 are obvious over the teachings of WO.

With respect to the rejections of claims as being indefinite, applicants explain that the instant amendment clarifies that the matrix is formed at a temperature above said

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matrix's melting temperature and that the drug crystals are coated with the surfactant.

However, instant claim 1 (as amended) still recites "said drug crystals coated said surfactant", which does not in any way reflect that the drug crystals are coated "with" the surfactant and instead the other way. Furthermore, it is unclear from instant claim 1 whether applicants claim a matrix, which after the formation results in formation of drug crystals coated with surfactant or a matrix and separately a component made of drug crystals coated with surfactant. Hence the rejection is maintained.

Examiner notes that instant amendment cites a serial number that does not match with the instant application serial number or docket number. It is suggested that applicants make note of the same for future communication.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

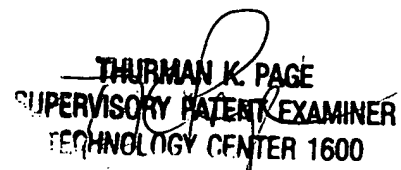
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615

May 16, 2005



THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600